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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/663,600	09/15/2000	Jean-Baptiste Dumas Milne Edwards	31.US3.CIP	2172

7590 11/26/2001

David L Bradfute
Vice President Intellectual Property
875 Prospect Street
Suite 206
La Jolla, CA 92037

EXAMINER
O HARA, EILEEN B

ART UNIT	PAPER NUMBER
1646	9

DATE MAILED: 11/26/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/663,600	EDWARDS ET AL.	
	Examiner	Art Unit	
	Eileen B. O'Hara	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-15* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   A. Claims 1-7 and 12-14, in so far as they are drawn to polynucleotides, vectors, host cells and a method of producing polypeptides, classified in class 536, subclass 23.5, class 435, subclasses 320.1, 252.3 and 69.1.

   B. Claims 8-11, in so far as they are drawn to polypeptides, classified in class 530, subclass 350, for example.

   C. Claim 15, in so far as it is drawn to antibodies to, classified in class 530, subclass 388.22, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions A and B are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polynucleotide is related to the polypeptide by virtue of encoding the same. The polynucleotides have utility for the recombinant production of protein in a host cell. Although the polynucleotides and proteins are related since the polynucleotides encode the specifically claimed proteins, they are distinct inventions because the protein products can be made by another materially different process, such as by synthesis or purification from the natural source. Further, the polynucleotides may be used for processes other than the production of proteins, such as nucleic acid hybridization assays and gene therapy.

The proteins of invention B are related to the antibodies of invention C by virtue of being the cognate antigen, necessary for the production of the antibodies. Although the protein and antibody are related due to the necessary stearic complementarity of the two, they are distinct inventions because they are physically and functionally distinct chemical entities, and because the protein can be used in another and materially different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right, or to assay or purify the protein.

Inventions A and C are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polynucleotides and antibodies are distinct inventions because they are structurally and functionally distinct chemical

Further Restriction Within Group A

2. Applicants' claims are drawn to numerous patentably distinct nucleic acid sequences. If group A is elected, further restriction *within* the group is required, as follows:

The claims are drawn to numerous patentably distinct nucleic acids, each of which constitutes a patentably distinct product. Applicant is required to elect a single invention of a nucleic acid, selected from the group consisting of: (i.e. elect one from the following Markush group):a nucleic acid comprising a polynucleotide having the sequence shown in SEQ ID NOS: 134-180 or 228, respectively, or encoding a protein selected from the group comprising SEQ ID NOS: 181-227 or 229.

Further Restriction Within Group B

3. Applicants' claims are drawn to numerous patentably distinct polypeptide sequences. If group B is elected, further restriction *within* the group is required, as follows:
The claims are drawn to numerous patentably distinct polypeptide sequences, each of which constitutes a patentably distinct product. Applicant is required to elect a single invention of a polypeptide, selected from the group consisting of: (i.e. elect one from the following Markush group):a polypeptide comprising an amino acid sequence shown in SEQ ID NOS: 181-227 or 229.

Further Restriction Within Group C

4. Applicants' claims are drawn to numerous patentably distinct antibodies to polypeptide sequences. If group C is elected, further restriction *within* the group is required, as follows:
The claims are drawn to numerous patentably distinct antibodies to specific polypeptide sequences, each of which constitutes a patentably distinct product. Applicant is required to elect a single invention of an antibody to a single polypeptide, selected from the group consisting of: (i.e. elect one from the following Markush group): an antibody to a polypeptide having an amino acid sequence shown in SEQ ID NOS: 181-227 or 229.

Applicant is advised that this is not a species election.

Although the classifications these various nucleic acid, proteins and antibodies are overlapping, for instance 536/23.1 or 530/350, each represents a patentably distinct product, with

different sequences and structures and with distinct physical and functional characteristics. For example, the 50 nucleic acids encoding the 50 proteins are different genes found in different chromosomal locations and encode proteins that are structurally and functionally distinct, and the antibodies to these 50 proteins are therefore structurally and functionally distinct. Further, the search for more than one product would be burdensome, because, in the case of the nucleic acid sequences, many are claimed not by nucleic acid sequence, but by the sequence of the protein encoded thereby, and requires a search of the corresponding region of the nucleic acid as well as a 'reverse translation' search of the corresponding region of the protein, such that each individual sequence requires two sequence searches which are not required for any of the other sequences. Accordingly, restriction is proper.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara whose telephone number is (703) 308-3312. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne L. Eyler can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D.
November 20, 2001